Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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20 January 2017

Dear Ms Henderson

Coroners and Justice Act 2009 – Regulation 28 Report following the Inquest into the death of Mrs Marjorie Cybil BASSENDINE

Thank you for your letter dated 30th November 2016, enclosing your Report under Regulation 28 following the Inquest into the death of Mrs Marjorie Cybil BASSENDINE.

I can confirm that the details of your report have been added onto our Adverse Drug Reaction database, under the reference number [redacted]

In your report you raise concerns regarding the combination of olanzapine, mirtazapine and indapamide increasing the risk of developing long QT syndrome.

We have reviewed the product information (Summary of Product Characteristics [SmPC] and Patient Information Leaflet) of olanzapine, mirtazapine and indapamide and are satisfied that all three contain appropriate warnings regarding the risk of QT prolongation, particularly when used with other medication that also causes QT prolongation. Details of the relevant warnings are included in Annex A.

Although only the indapamide SmPC specifically mentions monitoring of patients, including conducting ECG monitoring, the SmPCs for mirtazapine and olanzapine both advise the use of "caution" when prescribing in patients with known risk factors for QT prolongation including concomitant use of other medication known to cause QT prolongation. The decision to prescribe a particular medicine or combination of medicines is the responsibility of the prescribing clinician who is in the best position to consider the balance of risks and benefits for the individual patient. The MHRA cannot comment on individual prescribing decisions.

In conclusion, all three medicines' SmPCs already include warnings regarding the risk of QT prolongation, particularly when these medicines are used in combination with other medicines which also cause QT prolongation. On review of the warnings we consider them to be appropriate and to reflect the available data for the individual products.

Therefore we are not currently proposing any regulatory action to change these warnings. However we will keep this issue under review, and consider the need for further action or communications should the picture change.

Yours sincerely,

Dr Ian Hudson,
Chief Executive Officer
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